

Atty. Docket No: 47506 (47843)

#10

ent application of

MARCHIONNI, MARK et al.

Serial No. 09/756,481

Filed: January 8, 2001

For: METHODS FOR TREATING NEUROLOGICAL INJURIES AND DISORDERS

### STATEMENT TO SUPPORT FILING AND SUBMISSION IN ACCORDANCE WITH 37 C.F.R. §§ 1.821-1.825

Assistant Commissioner for Patents Washington, D.C. 20231
Box SEQUENCE

Sir:

In connection with a Sequence Listing submitted concurrently herewith, the undersigned hereby states that:

- the submission, filed herewith in accordance with 37 C.F.R. § 1.821(g), does not include new matter;
- 2. the content of the attached paper copy and the attached computer readable copy of the Sequence Listing, submitted in accordance with 37 C.F.R. § 1.821(c) and (e), respectively, are the same; and
- 3. all statements made herein of their own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United

Serial No. 09/756,481

States Code and that such willful false statements may jeopardize the validity of the application or any patent resulting therefrom.

Respectfully submitted,

A. Coburn

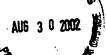
HARBOR CONSULTING

Intellectual Property Services 1500A Lafayette Road Suite 262 Portsmouth, N.H. 800-318-3021



záctitioner's Docket No. \_

**PATENT** 



#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

re application of:

M. Marchionni et al.

Application No.:

09/756,481

GROUP:

1614

Filed:

January 18, 2001

**EXAMINER:** 

Not Yet Assigned

For:

METHODS FOR TREATING NEUROLOGICAL INJURIES AND DISORDERS

**Assistant Commissioner for Patents** 

Washington, D.C. 20231

**BOX: PCT** 

#### SUBMISSION OF "SEQUENCE LISTING," COMPUTER READABLE COPY, AND/OR AMENDMENT PERTAINING THERETO FOR BIOTECHNOLOGY INVENTION CONTAINING NUCLEOTIDE AND/OR AMINO ACID SEQUENCE

	(check and complete	this item, if applicable)
1. [	X] This replies to the Office Letter DATED	July 3, 2002
NOTE	y	adequate identification of the original papers should be made, e.g. vention, the filing date based on the "Express Mail" procedure, the torney's docket number added.
	[X] A copy of the Office Letter is enclosed	sed.
1	IDENTIFICATION OF PER	RSON MAKING STATEMENT
2. I	,Christine C. O'Day (type or print name of	of person signing below)
-	CERTIFICATE OF MAILING/	TRANSMISSION (37 C.F.R. 1.8(a))
I herel	by certify that, on the date shown below, this corresponde	ence is being:
	MAILING	FACSIMILE
[X]	deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C.	[ ] transmitted by facsimile to the Patent and Trademark Office.
	20231.	Jusan M Oillon
	•	Signature
Date:	8/27/02	Susan M. Dillon
		(type or print name of person certifying)

(Submission-Nucleotide and/or Amino Acid Sequence--page 1 of 5)

state the following:

#### ITEMS BEING SUBMITTED

3.	Sub	omitted herewith is/are:			
			(check each item as a	pplicable)	
	A.	Each "Sequence		for amino acid sequence(s) in this apparate identifier as required in 37 C.F.J. 1.823.	
	B.		the description and/or claims gned identifier, as required in	s, wherein reference is made to the sea 37 C.F.R. Section 1.821(d).	quence by
	C.			or this application in computer readable. R. Sections 1.821(e) and 1.824.	le form, ii
	D.			be with 37 C.F.R. Section 1.821(e), the oplication identified as follows:	compute
		In re application of Application No.: 0 Filed: For:		Group No.: Examiner:	
Ide		e Computer readable er(s)" of the application		er application corresponds to the	"Sequence
C	omp	outer Readable Form		"Sequence Id	lentifier"
(0	ther	application)		(this app	olication)
NO	TE:	application of the applica readable form in lieu of file be accompanied by a letter	nt on file in the Office, referenc ing a duplicate computer readabl	be identical with the computer readable forn ce maybe made to the other application an le form in the new application. The new appli er application and computer readable form, be	nd compute ication sha
	E.		the content of each "Sequithe same, as required in 37 (	uence Listing" submitted and each C.F.R. Section 1.821(g).	compute
			tatement is not made by a price is verified as required in 37	person registered to practice before to C.F.R. Section 1.821(b).	he Office

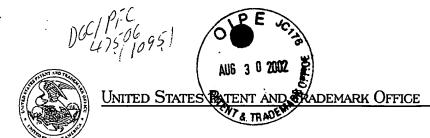
(Submission-Nucleotide and/or Amino Acid Sequence--page 2 of 5)

F. [X] Because this submission is made in fulfilling the requirement under 37 C.F.R. Section 1.821(g), a statement that the submission includes no new matter.
[ ] Because the statement is not made by a person registered to practice before the Office the statement is verified, as required in 37 C.F.R. Section 1.821(g).
STATEMENT THAT "SEQUENCE LISTING" AND COMPUTER READABLE COPY ARE THE SAME AND/OR THAT PAPERS SUBMITTED INCLUDES NO NEW MATTER
4. I hereby state:
(complete applicable item A and/or B)
A. [X] Each computer readable form submitted in this application, including those forms requested be transferred from applicant's other application, is the same as the "Sequence Listing" to while it is indicated to relate.
B. [X] All papers accompanying this submission, or for which a request for transfer from applican other application, introduce no new matter.
STATUS
5. Applicant is
[X] a small entity. [ ] other than a small entity.
EXTENSION OF TERM
NOTE: "Extension of Time in Patent Cases (Supplement Amendments) If a timely and complete response has been filed after Non-Final Office Action, an extension of time is not required to permit filing and/or entry of an additional amendment after expiration of the shortened statutory period.
If a timely response has been filed after a Final Office Action, an extension of time is required to permit filing and/or entry of an additional amendment after expiration of the shortened statutory periunless the timely-filed response placed the application in condition for allowance. Of course, if a Notice of Appeal heen filed within the shortened statutory period, the period has ceased to run." Notice of Dec. 10, 1985 (1061 O.G. 34-35)
NOTE: See 37 C.F.R. Section 1.645 for extensions of time in interference proceedings and 37 C.F.R. Section 1.550(c) j extensions of time in reexamination proceedings.
7. The proceedings herein are for a patent application and the provisions of 37 C.F.R. Section 1.136 apply
(complete (a) or (b) as applicable)
(a) [ ] Applicant petitions for an extension of time under 37 C.F.R. Section 1.136 (fees: 37 C.F.I Section 1.17(a)(1)-(4)) for the total number of months checked below:
(Submission-Nucleotide and/or Amino Acid Sequence—page 3 of

[ ] [ ] [ ]	Extension (months) one month two months three months four months	Fee for other than small entity  \$ 110.00 \$ 400.00 \$ 920.00 \$1,440.00	Fee for small entity  \$ 55.00 \$ 200.00 \$ 460.00 \$ 720.00									
į J	Tour monuis	\$1,770.00	\$ 720.00									
Fee \$												
If an additional extension of time is required, please consider this a petition therefor.												
(check and complete the next item, if applicable)												
[ ] An extension for months has already been secured, and the fee paid therefor of \$ is deducted from the total fee due for the total months of extension now requested.												
Extension fee due with this request \$												
		OR										
(b) [X	being made to pro		m is required. However, this conditional petition is nat applicant has inadvertently overlooked the need									
		FEE PAYN	MENT									
8. [] At	tached is a check in	the sum of \$										
			C m									
	large Account No duplicate of this tran		f\$									
-		FEE DEFIC	TENCY									
•		1222210										
NOTE: If there is a fee deficiency and there is no authorization to charge an account, additional fees are necessary to cover the additional time consumed in making up the original deficiency. If the maximum, six-month period has expired before the deficiency is noted and corrected, the application is held abandoned. In those instances where authorization to charge is included, processing delays are encountered in returning the papers to the PTO finance Branch in order to apply these charges prior to action on the cases. Authorization to charge the deposit account for any fee deficiency should be checked. See the Notice of April 7, 1986, 1065 O.G. 31-33.												
10. [X] If any additional extension and/or fee is required, charge Account No04-1105												
SIGNATURE(s)												

(Submission-Nucleotide and/or Amino Acid Sequence—page 4 of 5)

	Consine C. O Day
	(type or print name of person signing statement)
	Ohior C.on
8-27-02	Signature
Date EDWARDS & ANGELL, LLP P.O. Box 9169	
P.O. Address of Signatory  Boston, MA 02209	
(If applicable)	<ul><li>[ ] Inventor</li><li>[ ] Assignee of complete interest</li><li>[ ] Person authorized to sign on behalf of assignee</li></ul>
Tel. No.: (617) 439-4444	[X] Practitioner of record
Reg. No. 38,256	[ ] Filed under Rule 34(a)
Customer No.: 21874	[ ] Registration No. [ ] Other
(complete	e the following, if applicable)
(type name of assignee)	_
Address of assignee	
Title of person authorized to sign on behalf of assignee	
A "STATEMENT UNDER 37 C.F.R. Section Assignment recorded in PTO on	• •
Reel Frame _	
Reci Frame_	



COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

APPLICATION NUMBER

FILING/RECEIPT DATE

FIRST NAMED APPLICANT

ATTORNEY DOCKET NUMBER

09/756.481

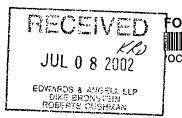
01/08/2001

Mark Marchionni

47506 (71095)

**CONFIRMATION NO. 4213** 

Dike, Bronstein, Roberts & Cushman Intellectual Property Practice Group Edwards & Angell, LLP P.O. Box 9169 Boston, MA 02209



FORMALITIES LETTER

OC000000008358557\*

Date Mailed: 07/03/2002

# NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant is given **TWO MONTHS FROM THE DATE OF THIS NOTICE** within which to file the items indicated below to avoid abandonment. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of
the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as
indicated on the attached copy of the marked -up "Raw Sequence Listing." Applicant must provide a
substitute computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content
of the sequence listing information recorded in computer readable form is identical to the written (on paper
or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR
1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d).

For questions regarding compliance to these requirements, please contact:

- For Rules Interpretation, call (703) 308-4216
- To Purchase Patentin Software, call (703) 306-2600
- For Patentin Software Program Help, call (703) 306-4119 or e-mail at patin21help@uspto.gov or patin3help@uspto.gov

A copy of this notice <u>MUST</u> be returned with the reply.

Customer Service Center

Initial Patent Examination Division (703) 308-1202

PART 1 - ATTORNEY/APPLICANT COPY

Edwards & Angell LLF

Dike, Bronstein, Roberts & Coshotte

101 Federal St. Boston, MA 02110

Sequence distin

Date Rec'd\_\_\_2

Docketed For Jep. 3, 2002 - Jun.

Approved m 7/5/er



ERROR DETECTED

SUGGESTED CORRECTION

SERIAL NUMBER: 09 15 6 481 A

## ATTN: NEW RULES CASES: PLEASE DISREGARD ENGLISH "ALPHA" HEADERS, WHICH WERE INSERTED BY PTO SOI

1 Wrapped Nucleics Wrapped Aminos	The number/text at the end of each line "wrapped" down to the next line. This may occur if your file was retrieved in a word processor after creating it. Please adjust your right margin to .3; this will prevent "wrapping."
2 Invalid Line Length	The rules require that a line not exceed 72 characters in length. This includes white spaces.
3Misaligned Amino Numbering	The numbering under each 5th amino acid is missaligned. Do not use tab codes between numbers; use space characters, instead.
4Non-ASCII	The submitted file was not saved in ASCII(DOS) text, as required by the Sequence Rules. Please ensure your subsequent submission is saved in ASCII text.
5Variable Length	Sequence(s) contain n's or Xaa's representing more than one residue. Per Sequence Rules, each n or Xaa can only represent a single residue. Please present the maximum number of each residue having variable length and indicate in the <220>-<223> section that some may be missing.
6Patentin 2.0	A "bug" in Patentin version 2.0 has caused the <220><223> section to be missing from amino acid sequences(s) Normally, Patentin would automatically generate this section from the previously coded nucleic acid sequence. Please manually copy the relevant <220>-<223> section to the subsequent amino acid sequence. This applies to the mandatory <220>-<223> sections for Artificial or Unknown sequences.
7Skipped Sequences (OLD RULES)	Sequence(s) missing. If intentional, please insert the following lines for each skipped sequence:  (2) INFORMATION FOR SEQ ID NO:X: (insert SEQ ID NO where "X" is shown)  (i) SEQUENCE CHARACTERISTICS: (Do not insert any subheadings under this heading)  (xi) SEQUENCE DESCRIPTION:SEQ ID NO:X: (insert SEQ ID NO where "X" is shown)  This sequence is intentionally skipped
, ,	Please also adjust the "(ii) NUMBER OF SEQUENCES:" response to Include the skipped sequences.
8 Skipped Sequences (NEW RULES)	Sequence(s) missing. If Intentional, please insert the following lines for each skipped sequence. <210> sequence id number <400> sequence id number 000
9Usc of n's or Xaa's (NEW RULES)	Use of n's and/or Xaa's have been detected in the Sequence Listing.  Per 1.823 of Sequence Rules, use of <220>-<223> is MANDATORY if n's or Xaa's are present.  In <220> to <223> section, please explain location of n or Xaa, and which residue n or Xaa represents.
10Invalid <213> Response	Per 1.823 of Sequence Rules, the only valid <213> responses are: Unknown, Artificial Sequence, or scientific name (Genus/species). <220>-<223> section is required when <213> response is Unknown or is Artificial Sequence
11Use of <220>	Sequence(s) missing the <220> "Feature" and associated numeric identifiers and responses.  Use of <220> to <223> is MANDATORY if <213> "Organism" response is "Artificial Sequence" or "Unknown." Please explain source of genetic material in <220> to <223> section.  (See "Federal Register," 06/01/1998, Vol. 63, No. 104, pp. 29631-32) (Sec. 1.823 of Sequence Rules)
12Patentin 2.0 "bug"	Please do not use "Copy to Disk" function of Patentin version 2.0. This causes a corrupted file, resulting in missing mandatory numeric identifiers and responses (as indicated on raw sequence listing). Instead, please use "File Manager" or any other manual means to copy file to floppy disk.
13Misuse of n	in can only be used to represent a single nucleotide in a nucleic acid sequence. N is not used to represent any value not specifically a nucleotide.

AMC/MH - Biotechnology Systems Branch - 08/21/2001

The type of errors shown exist throughout the Sequence Listing. Please check subsequent sequences for similar errors.



OIPE

RAW SEQUENCE LISTING DATE: 10/02/2001 PATENT APPLICATION: US/09/756,481A TIME: 11:48:10

Input Set : A:\47506-sequence.txt

Output Set: N:\CRF3\10022001\1756481A.raw

```
3 <110> APPLICANT: Mark Marchionni
              Michael Jarpe
              Ted Ebendal
      7 <120> TITLE OF INVENTION: METHODS FOR TREATING NEUROLOGICAL
              INJURIES AND DISORDERS
     10 <130> FILE REFERENCE: 47506 (71095)
     12 <140> CURRENT APPLICATION NUMBER: 09/756,481A
C--> 13 <141> CURRENT FILING DATE: 2001-08-30
                                                                        Does Not Comply
     15 <150> PRIOR APPLICATION NUMBER: PCT/US99/15106
                                                                    Corrected Diskette Needed
     16 <151> PRIOR FILING DATE: 1999-07-02
     18 <150> PRIOR APPLICATION NUMBER: 60/091,791
     19 <151> PRIOR FILING DATE: 1998-07-06
     21 <160> NUMBER OF SEQ ID NOS: 2
    26 <211> LENGTH: 1387

27 <212> TYPE: DNA

28 <213> ORGANISM: Artificial Sequence

30 <220> FEATURE:

31 <221> NAME/KEY: CDS

32 <222> NAME/KEY: CDS
     32 <222> LOCATION: (218)...(1288-)
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                                                                                 120
         ccaggacete aaageacece egacetaagg teaceageee actggeeeca gaegeagtgg
                                                                                 180
         gctccgctga ctctcttgga cacctcctgg gaggaaa atg ctc cct gtc tgc cat
                                                                                 235
                                                   Met Leu Pro Val Cys His
     39
     40
                                                                                 283
        egt ttt tgc gac cac ctc ctc ctc ctg ctc ttg ctg ccc tcg acg acc
         Arg Phe Cys Asp His Leu Leu Leu Leu Leu Leu Pro Ser Thr Thr
     44
                      10
                                           15
         ctg gcc ccc gcg cca gca tcc atg ggc ccc gct gcc gcc ctg ctc cag
                                                                                 331
         Leu Ala Pro Ala Pro Ala Ser Met Gly Pro Ala Ala Leu Leu Gln
     47
     48
                                       30
                  25
     50
         gtt ctt ggg ctt ccc gaa gcg ccc cgg agc gtc ccc aca cac cga cct
                                                                                 379
         Val Leu Gly Leu Pro Glu Ala Pro Arg Ser Val Pro Thr His Arg Pro
         gtg cct cct gtc atg tgg cgc cta ttc cgt cgc cgt gac ccc cag gag
                                                                                 427
     54
         Val Pro Pro Val Met Trp Arg Leu Phe Arg Arg Arg Asp Pro Gln Glu
     55
                                                   65
                              60
     57
         gcc aga gtg gga cgc cct ctg cgg cca tgc cac gtg gag gaa cta ggg
        Ala Arg Val Gly Arg Pro Leu Arg Pro Cys His Val Glu Glu Leu Gly
                                               80
        gtc gcc gga aac att gtg cgc cac atc ccc gac agc ggt ctg tcc tcc
                                                                                 523
     61
         Val Ala Gly Asn Ile Val Arg His Ile Pro Asp Ser Gly Leu Ser Ser
     62
                                                              100
                                           95
     63
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RAW SEQUENCE LISTING
PATENT APPLICATION: US/09/756,481A

DATE: 10/02/2001
TIME: 11:48:10

Input Set : A:\47506-sequence.txt

Output Set: N:\CRF3\10022001\1756481A.raw

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66	Arg	${\tt Pro}$	Ala	Gln	Pro	Ala	Arg		Ser	Gly	Leu	Cys		Glu	Trp	Thr	
67			105					110					115				
69			ttt														619
70	Val	Val	Phe	Asp	Leu	Ser	Asn	Val	Glu	Pro	Thr		Arg	Pro	Thr	Arg	
71		120					125					130					
73			tta														667
74	Ala	Arg	Leu	Glu	Leu	Arg	Leu	Glu	Ala	Glu	Cys	Glu	Asp	Thr	Gly		
75	135					140					145					150	_
77			cta														715
78	Trp	Glu	Leu	Ser		Ala	Leu	Trp	Ala	_	Ala	Glu	His	Pro	_	Pro	
79					155					160					165		
81			ctg														763
82	Glu	Leu	Leu	_	Val	Pro	Ala	Pro		Gly	Val	Leu	Leu		Ala	Asp	
, 83				170					175					180			
85			ggg														811
86	Leu	Leu	Gly	Thr	Ala	Val	Ala		Asn	Ala	Ser	Val		Cys	Thr	Val	
87			185					190					195				
89			gcg														859
90	Arg	Leu	Ala	Leu	Ser	Leu		Pro	Gly	Ala	Thr		Ala	Cys	Gly	Arg	
91		200					205					210					
93			gag														907
94		Ala	Glu	Ala	Ser		Leu	Leu	Val	Thr		Asp	Pro	Arg	Leu		
95	215					220					225					230	
97			ccg														955
98	Pro	Leu	Pro	Arg		Arg	Arg	His	Thr		Pro	Arg	Val	Glu		Gly	
99					235					240					245		1000
101																gag	1003
102	Pro	Val	. Gly			Arg	Thr	Arg	-		Hls	; val	. Ser			Glu	
103				250					255					260			1051
105					_					-	_					aac	1051
106	val	. GIŞ	_		Arg	Trp	vaı			Pro	Arg	GIA			Ald	Asn	
107			265					270					275				1000
109																ggc	1099
110	Pne	_		СТУ	Thi	Cys			Pro	GLU	THI			СТА	PIC	Gly	
111		280					285		~+~			290					1117
113		-		_				-		-	-			_		gca	1147
114	-		Pro	АТа	Leu			Ата	vaı	. Leu	_		Leu	. Met	. HIS	Ala	
115	295					300		~~~	. +		305		. ~+~		~~~	310	1105
117																cgt	1195
118	Ата	ATS	Pro	Thr			Ala	GIY	Ser			Сув	val	PIO		Arg	
119	_4_				315					320		~~+	~~~		325		1243
121																gtc	1243
122	Leu	ser	PIO			var	ьeu	Pne	335	_	ASII	ser	ASP	340		Val	
123	<b></b>		05.5	330		~~~	a + ~	a+-			a	+~+	~~~			•	1288
125			cac														1200
126 127	rea	AI 9	His 345	_	GIU	АБР	met	350		vsb	Gru	СУБ	355		мтд		
127	+ ~-	0000			2000	++ +	~~~			0020	uu a a	227			+a++	tgttca	1348
129	Lga	ccac	ceg	yyac	accc	נו נ	cayy	yacc	y cc	Cuac	ycaa	aay	cayy	yac	LyLL	cyclica	1340

RAW SEQUENCE LISTING

PATENT APPLICATION: US/09/756,481A

DATE: 10/02/2001 TIME: 11:48:10

Input Set : A:\47506-sequence.txt

Output Set: N:\CRF3\10022001\1756481A.raw

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RAW SEQUENCE LISTING

DATE: 10/02/2001

PATENT APPLICATION: US/09/756,481A

TIME: 11:48:10

Input Set : A:\47506-sequence.txt

Output Set: N:\CRF3\10022001\1756481A.raw

180					325					330					335		
181	Asn S	Ser	Asp	Asn	Val	Val	Leu	Arg	His	Tyr	Glu	Asp	Met	Val	Val	Asp	
182				340					345					350			
183	Glu C	Cys	Gly	Cys	Arg												
184			355														

VERIFICATION SUMMARY

DATE: 10/02/2001 TIME: 11:48:11

PATENT APPLICATION: US/09/756,481A

Input Set : A:\47506-sequence.txt

Output Set: N:\CRF3\10022001\I756481A.raw

L:13 M:271 C: Current Filing Date differs, Replaced Current Filing Date

L:34 M:258 W: Mandatory Feature missing, <223> OTHER INFORMATION: L:137 M:258 W: Mandatory Feature missing, <220> FEATURE:

L:137 M:258 W: Mandatory Feature missing, <223> OTHER INFORMATION:

STATISTICS SUMMARY

DATE: 10/02/2001

PATENT APPLICATION:

US/09/756,481A

TIME: 11:48:11

Input Set : A:\47506-sequence.txt

Output Set: N:\CRF3\10022001\I756481A.raw

Application Serial Number: US/09/756,481A

Alpha or Numeric: Numeric

Application Class:

Application File Date: 08-30-2001

Art Unit: OIPE

Software Application: FastSeq Total Number of Sequences: 2 Total Nucleotides: 1387 Total Amino Acids: 357

Number of Errors: 0 Number of Warnings: 3 Number of Corrections: 1

#### MESSAGE SUMMARY

258 W: 3 (Mandatory Feature missing)
271 C: 1 (Current Filing Date differs)